

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) for its Complaint against Defendant Roxane Laboratories, Inc. (“Roxane”) alleges as follows:

I. THE PARTIES

1. Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave NW, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including FANAPT® (iloperidone oral tablets), for the treatment of schizophrenia.

2. On information and belief, Roxane is a Nevada corporation, with a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. On information and belief, Roxane is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of Delaware and throughout the United States.

II. NATURE OF THE ACTION

3. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, *et seq.*) based upon Roxane's infringement of claim 1 of Vanda's U.S. Patent No. 9,138,432 ("the '432 patent"), which relates to the field of schizophrenia treatment.

4. Roxane has filed an Abbreviated New Drug Application (the “Roxane ANDA”) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the “FFDCA”), to obtain approval to commercially manufacture and sell generic iloperidone tablets in their 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia.

5. Roxane infringes claim 1 of the ’432 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of the Roxane ANDA, including its filing of any amendments or supplements thereto, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic iloperidone for the treatment of schizophrenia prior to the expiration of the ’432 patent, or any extensions thereof. Roxane will infringe claim 1 of the ’432 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia according to the methods of the ’432 patent prior to the expiration of that patent, or any extensions thereof.

III. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over Vanda’s patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Roxane by virtue of the fact that, *inter alia*, Roxane has committed, induced, contributed to, aided, abetted, or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Vanda, a Delaware corporation. This Court has personal jurisdiction over Roxane for the additional reasons set forth below.

8. This Court also has personal jurisdiction over Roxane, by virtue of, *inter alia*, its activities (*e.g.*, filing the Roxane ANDA with a Paragraph IV certification and sending

notice of that Paragraph IV certification) that were purposefully directed to the State of Delaware. Vanda is incorporated in Delaware, and thus the consequences of Roxane's actions were (and will be) suffered in Delaware. Roxane knew or should have known that Vanda is a Delaware corporation and thus Roxane knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

9. This Court also has personal jurisdiction over Roxane because it was reasonably foreseeable that Roxane would be sued in this District where Vanda is organized and where related ANDA litigation over generic iloperidone, including litigation based on infringement of a patent in the same family as the '432 patent, namely U.S. Patent No. 8,586,610 ("the '610 patent"), had already been filed (C.A. Nos. 13-1973 (GMS); 14-757 (GMS) (consolidated)). Roxane knew that Vanda is a Delaware corporation and Roxane knew that there is related ANDA litigation over generic iloperidone, including litigation based on infringement of the related '610 patent, pending in Delaware.

10. On information and belief, Roxane develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and throughout the United States. Thus, on information and belief, Roxane does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. These continuous and systematic contacts, including, but not limited, to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Roxane.

11. On information and belief, Roxane has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Roxane has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this

jurisdiction. Specifically, Roxane admitted jurisdiction (for purposes of the litigation) and filed counterclaims in at least the following actions in this Court: *Vanda Pharm. Inc. v. Roxane Labs., Inc.*, 13-cv-1973 (D. Del.); *Eisai Co. v. Roxane Labs., Inc.*, 13-cv-1284 (D. Del.); *Glaxo SmithKline LLC v. Roxane Labs., Inc.*, 11-cv-542 (D. Del.); *Abbott Labs. v. Roxane Labs., Inc.*, 10-cv-998 (D. Del.).

12. On information and belief, Roxane, following any FDA approval of the Roxane ANDA, will sell the generic product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

IV. THE PATENT-IN-SUIT – U.S. PATENT NO. 9,138,432

14. The allegations of ¶¶ 1-13 are incorporated herein by reference.

15. Vanda is the owner of all rights, title and interest in the '432 patent, entitled "Methods for the Administration of Iloperidone." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '432 patent on September 22, 2015, to Curt D. Wolfgang and Mihael H. Polymeropoulos, which was assigned to Vanda. A true and correct copy of the '432 patent is attached to this Complaint as Exhibit A.

16. The '432 patent claims "[a] method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising: administering to the patient a dose of iloperidone that is 24 mg/day if, and because, the patient is not being treated with fluoxetine; and administering to the patient a dose of iloperidone that is 12 mg/day if, and because, the patient is being treated with fluoxetine."

17. On May 6, 2009, FDA approved Vanda's new drug application 22-192 for FANAPT® (iloperidone oral tablets) in their 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg

strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of schizophrenia (“FANAPT® NDA”).

18. The prescribing information for FANAPT® (“FANAPT® Label”) instructs physicians that “The maximum recommended dose is 12 mg twice daily (24 mg/day)” and that “FANAPT dose should be reduced by one-half [*i.e.*, the dose should be reduced to 6 mg twice daily (12 mg/day)] when administered concomitantly with strong CYP2D6 inhibitors such as fluoxetine or paroxetine.”

19. On information and belief, the Roxane ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to administer either the maximum recommended dose of 24 mg/day if the patient is not being treated with fluoxetine or a halved dosage of 12 mg/day if the patient is being treated with fluoxetine.

20. Thus, the use of FANAPT® (iloperidone oral tablets) and any generic iloperidone for the treatment of schizophrenia is covered by the ’432 patent, and Vanda has the right to enforce the ’432 patent.

21. FDA listed the ’432 patent in the Orange Book for FANAPT® in its 1 mg, 2 mg, 4 mg, 6mg, 8 mg, 10 mg, and 12 mg strengths on September 23, 2015.

COUNT I
(INFRINGEMENT OF THE ’432 PATENT)

22. The allegations of ¶¶ 1-21 are incorporated herein by reference.

23. Roxane filed the Roxane ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic iloperidone for the treatment of schizophrenia before the expiration of the ’432 patent, and any extensions thereof.

24. On information and belief, Novartis Pharmaceutical Corp. (“Novartis”) received a letter dated October 17, 2013, stating that Roxane had filed the Roxane ANDA seeking approval to manufacture, use, offer to sell, and sell generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia before the expiration of U.S. Patent No. RE39,198 (the ’198 patent). Because the ’198 patent expires before the ’432 patent will expire, Roxane’s assertion that it intends to begin manufacture, use, sale, and offer for sale of generic iloperidone before the expiration of the ’198 patent confirms that it will also begin manufacture, use, sale, and offer for sale of generic iloperidone before the expiration of the ’432 patent.

25. On information and belief, the Roxane ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to administer either the maximum recommended dose of 24 mg/day if the patient is not being treated with fluoxetine or a halved dosage of 12 mg/day if the patient is being treated with fluoxetine.

26. Roxane infringes the ’432 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Roxane ANDA, including any amendments or supplements thereto, to FDA for generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia, which are covered by claim 1 of the ’432 patent.

27. Roxane’s participation in, contribution to, inducement of, aiding or abetting the submission of the Roxane ANDA to FDA constitutes direct, contributory, or induced infringement of claim 1 of the ’432 patent under 35 U.S.C. § 271(e)(2)(A).

28. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Roxane ANDA be a

date that is not earlier than the expiration of the '432 patent, or any later expiration of exclusivity for the '432 patent to which Vanda becomes entitled.

29. Vanda will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing or contributing to infringement of claim 1 of the '432 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

30. To the extent Roxane commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '432 PATENT)

31. The allegations of ¶¶ 1-30 are incorporated herein by reference.

32. On information and belief, Roxane intends to, and will manufacture, use, offer to sell, or sell within the United States, or import into the United States, generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths immediately and imminently upon FDA approval of the Roxane ANDA.

33. If Roxane manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths prior to the expiration of the '432 Patent for the methods of use claimed in that patent, Roxane will infringe claim 1 of the '432 Patent under 35 U.S.C. § 271 (a), (b), and/or (c).

34. An actual controversy has arisen and now exists between the parties concerning whether Roxane's generic iloperidone will infringe claim 1 of the '432 Patent.

35. An actual controversy has also arisen and now exists between the parties concerning whether Roxane's filing of the Roxane ANDA will infringe 35 U.S.C. § 271(e)(2)(A)

if Roxane amends the Roxane ANDA after the '432 Patent issued and was timely listed in the Orange Book and/or if Roxane issues a Paragraph IV certification regarding the '432 Patent.

36. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., the Court has the power to, and should, declare the rights of the parties regarding any infringement by Roxane of the '432 Patent.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Roxane and grant the following relief:

A. a judgment that Roxane infringes claim 1 of the '432 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Roxane ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia, including any amendments or supplements thereto, before the expiration of the '432 patent;

B. a judgment declaring that Roxane will infringe directly, contribute to, or induce the infringement of claim 1 of the '432 patent under 35 U.S.C. § 271(e)(2)(A) if Roxane amends the Roxane ANDA after the '432 Patent issued and was timely listed in the Orange Book or issues a Paragraph IV certification directed at that patent;

C. a judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of the products described in the Roxane ANDA would constitute infringement of claim 1 of the '432 patent, or inducement of or contribution to such conduct, by Roxane pursuant to 35 U.S.C. § 271 (a), (b), or (c);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Roxane ANDA for generic iloperidone be a date that is not

earlier than the date of the expiration of the '432 patent or any later period of exclusivity to which Vanda is or may become entitled;

E. a permanent injunction enjoining Roxane, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '432 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Roxane ANDA;

F. an order enjoining Roxane, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '432 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Roxane ANDA while the litigation is pending;

G. an assessment of pre-judgment and post-judgment interest and costs against Roxane, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284; and

H. such other and further relief as this Court may deem just and proper.

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